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(54) Title: AUDITIVE PROSTHESIS COMPRISING A CARRIER WHICH CAN BE IMPLANTED IN A COCHLEA <div data-bbox="370 1138 1230 1600" data-label="Image"> </div>		
(57) Abstract <p>An auditive prosthesis comprising an elongated carrier (31) which can be implanted in the scala tympani of a cochlea, which carrier is provided, over at least a part of its length, at a first side face with electrode elements and, at a second side face (32b) facing away from the first side face (32a), with an electric conductor. Said side faces are interconnected by a third side face (32c) and a fourth side face (32d), said first side face extending, in a state where the carrier is implanted in the scala tympani, opposite the basilar membrane of the cochlea. In order to achieve, after implantation, an information transfer to the auditory nerve which is as complete as possible, the third side face and the fourth side face of the carrier are arranged, over at least a part of the length of the carrier where electrode elements are present, at distances from each other which are at least substantially equal to corresponding dimensions of the scala tympani which are parallel to the basilar membrane. After implantation of the carrier, the scala tympani is at least substantially completely filled, over at least a part of the area extending between the fenestra cochlea and the helicotrema, in a zone extending parallel to the basilar membrane.</p>		

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Auditive prosthesis comprising a carrier which can be implanted in a cochlea.

The invention relates to an auditive prosthesis comprising an elongated carrier which can be implanted in the scala tympani of a cochlea, which carrier is provided, over at least a part of its length, with electrode elements at a first side face and, at a second side face facing away from the first side face, with an electric conductor, which side faces are
5 interconnected by a third side face and a fourth side face, the first side face extending, in a state in which the carrier is implanted in the scala tympani, opposite the basilar membrane of the cochlea.

Such an auditive prosthesis is known from WO 97/38653 (PHQ 96.025). The known prosthesis comprises a silicone carrier provided with a set of electrodes, which silicone
10 carrier can be operatively implanted in a scala tympani of a cochlea to improve the hearing capacity of a hearing-impaired person. Said set includes a series of electrode contacts arranged on a side of the carrier and a central electrode arranged on an opposite side. After implantation of the carrier, electric currents can be sent through the electrodes, in dependence upon received sound signals, to stimulate nerve fibers of the auditory nerve present in the modioli so as to
15 induce electrical signals into the auditory nerve. Via nerve fibers, these signals are guided to the brain to interpret sound signals.

Said known prosthesis is provided with a swelling member which is provided on a side face interconnecting the two above-mentioned sides, which swelling member, after implantation of the carrier, serves to urge the carrier against the modioli. Although a
20 reasonable stimulation of the auditory nerve can be achieved in this way, relatively many electric currents between the electrode contacts and the central electrode still run via the perilymph, so that considerable parts of the electric currents supplied for stimulation are lost and hence only a limited information transfer to the neural system in the modioli takes place.

It is an object of the invention to improve the auditive prosthesis mentioned in the opening paragraph in such a manner that, after implantation, said prosthesis can highly
25 efficiently transfer information to the auditory nerve.

To achieve this, the auditive prosthesis in accordance with the invention is characterized in that, over at least a part of the length of the carrier where electrode elements are present, the third side face and the fourth side face of the carrier are situated at distances

from each other which are at least substantially equal to corresponding dimensions of the scala tympani which extend parallel to the basilar membrane, in order to at least substantially completely fill the scala tympani, after implantation, over at least a part of the area extending between the fenestra cochlea (round window) and the helicotrema in a zone extending parallel
5 to the basilar membrane.

The auditive prosthesis in accordance with the invention is intended to bring about a sound perception in patients who are hard of hearing, very hard of hearing or deaf, which sound perception may give rise to the hearing of speech by means of an efficient electrical stimulation of the auditory nerve.

10 The above-mentioned carrier with electrode elements forms an internally implantable part of the auditive prosthesis in accordance with the invention. The auditive prosthesis may additionally comprise an externally implantable part, which is provided with means for receiving sound signals and with a speech processor for converting these signals to electrical signals. By means of algorithms, the sound caught can be processed to imitate the
15 operation of a normal inner ear. Such a processing step may result in coded information which can be passed on to the internal part where this information is converted to electric currents between the electrode elements and the conductor present. The number of individually drivable electrode elements may range, for example between 28 and 35, although other numbers are possible too.

20 By means of the measure used in the auditive prosthesis it has been achieved that, after a correctly performed implantation, the first side face of the carrier faces the basilar membrane, the electrode elements being very close to the habenula perforations. The habenula perforations are openings in the bone structure bordering on the scala tympani, which openings guide the dendrites of the afferent nerve fibers of the internal hair cells along the
25 ganglion cells to the higher auditive centers in the brain. The applied measure leads to a well-definable interface between the carrier and the neural system, which can be attributed to the fact that the space of the scala tympani can be filled in such a way by a correctly implanted carrier that in the zone extending parallel to the basilar membrane there is no, or hardly any perilymph between the carrier and the partition of the scala tympani, so that the resistance path
30 between the electrode elements at the first side face and the conductor at the second side face is maximal. Consequently, the currents generated for stimulation are more efficiently used to stimulate the nerve fiber structure in the modiolis.

An embodiment of the auditive prosthesis in accordance with the invention is characterized in that, over at least the part of the carrier where electrode elements are present,

the first side face and the second side face of the carrier are at distances from each other which are at least substantially equal to corresponding dimensions of the scala tympani which extend transversely to the basilar membrane, in order to at least substantially completely fill the scala tympani, after implantation, over at least a part of the area extending between the fenestra
5 cochlea and the helicotrema in a zone extending transversely to the basilar membrane.

By means of the measure applied in this embodiment it is achieved, after a correct implantation of the carrier in the scala tympani, that the first face of the carrier, which is provided with electrode elements, lies against the basilar membrane and the adjoining part of the modiolis, in particular the laminae spiralis osseae, which has a favorable effect on the
10 transfer of electric currents from the electrode elements to the habenula perforations. Besides, electrode elements situated as closely to the nerve fibers as possible counteract disturbing channel interactions.

An embodiment of the auditive prosthesis in accordance with the invention is characterized as defined in claim 3.

15 An embodiment of the auditive prosthesis in accordance with the invention is characterized as defined in claim 4.

In the practical embodiments in accordance with claims 3 and 4, the carrier is optimally adapted to the anatomy of the cochlea of human beings.

In an embodiment of the auditive prosthesis in accordance with the invention
20 the first side face of the carrier is an at least substantially flat or, possibly, slightly curved surface, the electrode elements being provided with flat contact faces which are situated in or below the above-mentioned surface.

Consequently, the first side face does not have projecting parts, so that said face accurately corresponds to the shape of the inner side of the scala tympani which is situated
25 near the basilar membrane and the adjoining part of the modiolis, which, on the one hand, is important to preclude damage to the basilar membrane during the provision of the carrier and, on the other hand, has a favorable effect on the information transfer, after the provision of the carrier. If the contact faces do not extend in the surface of the carrier, they are preferably situated directly underneath said surface. This is the case, for example, if the electrode
30 elements are retained in the carrier by means of an overhanging edge of carrier material.

It is noted that the application of the measure in accordance with claim 1, whether or not in combination with the measure in accordance with claim 2, leads to a carrier which is relatively voluminous of itself and hence to an auditive prosthesis of which at least two side faces, even four side faces if the measure in accordance with claim 2 is applied, may

closely contact the partitions of the scala tympani during inserting the carrier into the scala tympani. It has nevertheless been found that this does not have any adverse effects for the patient if the implantation is carried out correctly and if a flat first side face is used. In addition, it has surprisingly been found that the prosthesis with a flat first side face can be
5 removed from the cochlea without damaging the scala tympani, more specifically the basilar membrane.

An embodiment of the auditive prosthesis is characterized in that the contact faces of the electrode elements are arranged according to a series extending in the longitudinal direction of the carrier, at least a number of the contact faces present being oval faces whose
10 longitudinal axes are oriented transversely to the longitudinal direction of the carrier. An advantage of this embodiment resides in that, in spite of a high density of electrode elements, the carrier has a relatively high flexibility, which is favorable during inserting the carrier into the spiral-shaped scala tympani. The applied measure also enables the use of relatively large contact faces, which has a favorable effect on the impedance between the contact faces and the
15 perilymph. In addition, the use of larger contact faces enables a smaller current density to be used, which is important in precluding undesirable electrochemical reactions at the location of the contact faces.

An embodiment of the auditive prosthesis in accordance with the invention is characterized in that the contact faces of the electrode elements have a rough surface. Contact
20 faces having a certain degree of roughness have a larger effective contact surface area and hence a lower impedance than smooth contact faces. Preferably, the contact faces of the auditive prosthesis are provided with a coating, in particular an impedance-reducing coating, such as iridium oxide, in which case the roughness also has a favorable effect on the adhesion of the coating. The electrode elements themselves are preferably made of an inert material,
25 such as platinum.

The invention further relates to a carrier which can suitably be used in the auditive prosthesis in accordance with the invention. The carrier in accordance with the invention is characterized as described in any one of the claims 1 through 7.

The invention further relates to an elongated, preferably pre-bent, carrier which
30 is provided over at least a part of its length, at a first side face, with electrode elements and which can be implanted in one of the tubular spaces, such as the scala tympani, the scala vestibuli or the scala media, of a cochlea. In order to enable the side face provided with electrode elements to connect closely, after the implantation of the carrier, to a corresponding wall part of the cochlea, the carrier in accordance with the invention is characterized in that the

first side face is an at least substantially flat or, possibly, slightly curved surface, the electrode elements being provided with flat contact faces situated in or below said surface.

Consequently, in said first side face there are no projecting parts, thereby counteracting damage of the cochlea during implantation, and enabling, after implantation, said side face to
5 be in close contact with an inner wall of the cochlea. The carrier in accordance with the invention thereby achieves the object that it should be possible, after implantation, to highly efficiently transfer information to the auditory nerve.

Preferably, the contact faces of the electrode elements are arranged in accordance with a series extending in the longitudinal direction of the carrier, at least a
10 number of the contact faces present being oval or oval-like faces having axes which are oriented transversely to the longitudinal direction of the carrier. The carrier will generally be provided at a second side face with one or more electric conductors to form a suitable electric circuit.

In an embodiment of the carrier in accordance with the invention, the contact
15 faces of the electrode elements have a rough surface.

With respect to the claims it is noted that various combinations of characteristics defined in the claims are possible.

These and other aspects of the invention will be apparent from and elucidated with reference to the embodiment(s) described hereinafter.

20

In the drawings:

Fig. 1 diagrammatically shows the anatomy of a human ear,

Fig. 2 is a diagrammatic, cross-sectional view of the scala tympani of the
25 cochlea of the human ear (the drawing is taken from Hatsushika et al., Dimensions of Scala Tympani, pp. 872, 876; Fifth International Symposium on Recent Advance in Otitis Media; May 20-23, 1991),

Fig. 3 is a perspective view of a part of an embodiment of the carrier in accordance with the invention,

30 Fig. 4 is a diagrammatic plan view of the embodiment shown in Fig. 3,

Fig. 5 is a diagrammatic bottom view of the embodiment shown in Fig. 3, and

Fig. 6 diagrammatically shows an embodiment of the auditive prosthesis in accordance with the invention.

The human ear diagrammatically shown in Figs. 1 and 2 comprises an outer ear with an auricle 1 and an auditory duct 3, a middle ear which borders on the outer ear by means of an eardrum 5 and which is provided with ossicles 7, and an inner ear with a cochlea 9. Said cochlea 9 is situated in the petrosal bone and is provided with a spiral-shaped network comprising the scala vestibuli 11 and the scala tympani 13, which are interconnected in the apex of the cochlea via the helicotrema 15. At the base of the cochlea 9 there are two windows, one of which, i.e. the oval window 17 in which one of the ossicles 7 fits, closes the scala vestibuli 11, and the other, i.e. the round window 19, which connects to the middle ear cavity, closes the scala tympani 13. Between these scalae, there is the scala media 21 with a sensorial organ, referred to as Corti's organ. The scala tympani 13 is filled with perilymph, which is a fluid whose ion composition resembles that of extracellular fluid. Between the scala media 21 and the scala tympani 13 extends the basilar membrane 23. The lamina spiralis osseae 25 of the modiolis 26 and the habenula perforations 27 are situated between the scala vestibuli 11 and the scala tympani.

The elongated pre-bent carrier 31, which is shown in Figs. 3, 4 and 5 and which includes electrode elements 33 is to be implanted in a cochlea, in particular in the scala tympani thereof. For clarity reference will be made, if necessary, to the cochlea 9 shown in Figs. 1 and 2. The carrier 31, which has a length l between its base 31a and its top 31b, is provided, in this example, with a carrier body 32 of silicones in which the electrode elements 33 as well as an electric conductor 35, which is embodied so as to be a longitudinal electrode, are provided. In this example, the length l is 29 mm. The electrode elements 33, which are provided with flat contact faces 33a, are situated at a first side face 32a of the carrier 31, while the electric conductor 35, which extends at least substantially throughout the length of the carrier 31, is situated at a second side face 32b facing away from the first side face 32a. For securing the electric conductor 35 and for giving the carrier 31 sufficient flexibility, the electric conductor 35 comprises, in this example, a number of electrical electrode faces 35a, which are arranged in series and which are preferably situated in or below the surface formed by the second side face 32b. The number of electrode faces amounts to 17. Said side faces 32a and 32b are interconnected by two further side faces, i.e. a third side face 32c and a fourth side face 32d.

The shape and dimensions of the carrier 31 in accordance with the invention are such that, after a correct implantation of the carrier 31 in the scala tympani 13, the first side face 32a extends opposite the basilar membrane 23 and constitutes a perfect interface with the neural system. For this purpose, the third side face 32c and the fourth side face 32d, viewed

over at least a substantial part of the length l of the carrier 31, are at mutual distances d_{34} , which are equal, or substantially equal, to the corresponding internal maximum width dimensions w of the scala tympani 13 which are oriented parallel to the basilar membrane 23. To this end, the first side face 32a and the second side face 32b, viewed over at least a

5 substantial part of the length l of the carrier 31, are additionally situated at mutual distances d_{12} which are equal, or substantially equal, to the corresponding internal maximum height dimensions h for the scala tympani 13 which extend transversely to the basilar membrane. In addition, the first side face 32a of the support 31 is embodied so as to be a flat surface, which is to be taken to mean a surface without projecting parts or elements.

10 The auditive prosthesis in accordance with the invention, as shown in Fig. 6, comprises, apart from said carrier 31, an electrical unit 41, a microphone 51 and a speech processor 61. In the implanted state, the carrier 31 and the unit are in the scala tympani 13, while the microphone 41 and the speech processor 51 are outside said scala tympani. During implanting the carrier 31, said carrier is slid into the scala tympani 13 via the round window

15 19 or via an opening which is operatively provided next to said window.

Hereinafter a further description of the carrier 31 will be given, with reference to the Figs. 3, 4 and 5. As will be obvious from the foregoing description, the carrier 31 has local transverse dimensions d_{34} over a part of its length l , which correspond to corresponding local width dimensions w of the scala tympani 13, and local height dimensions d_{12} which

20 correspond to corresponding local height dimensions h of the scala tympani 13. In this example, the carrier 31 has thirty one contact faces 32a. In the area indicated by m , i.e. the area measured along the longitudinal axis of the carrier 31, which is situated approximately centrally between the two outermost contact faces 32a, the dimension d_{12} is 800 μm and the dimension d_{34} is 1000 μm , in this example. Towards the base 31a, the dimensions d_{12} and d_{34}

25 increase gradually or stepwise to respectively 1000 μm and 1200 μm . Towards the top 31b, the dimensions d_{12} and d_{34} decrease gradually or stepwise to respectively 600 μm and 750 μm .

In the present example, the theoretically flat contact faces 33a are situated slightly below the theoretically flat surface of the first side face 32a. The electrode elements 33, as well as the associated contact faces 33a, are arranged in accordance with a series

30 extending in the longitudinal direction of the carrier 31, the contact faces 33a being embodied so as to be oval faces. With the exception of several contact faces situated near the top 31b, the contact faces have longitudinal axes l_c which are oriented transversely to the longitudinal direction of the carrier 31. In this example, these faces are essentially rectangular, yet provided with round end portions. In this example, the electrode elements are made of platinum, and a

thin coating of iridium oxide is applied to the slightly rough contact surfaces. The electrode elements each have a surface area of approximately 0.4 mm^2 .

It is noted that the invention is not limited to the examples shown herein. For example, carriers having a side face provided with a different number of contact faces fall within the scope of the invention. In addition, instead of flat side faces, one or more slightly curved side faces may be used. In general, the dimension d_{12} ranges between $700 \text{ }\mu\text{m}$ and $900 \text{ }\mu\text{m}$, the second side face 32b and the first side face 32a enclosing an average slope angle in the range between 0.5° and 1.5° . The dimension d_{34} generally ranges between $900 \text{ }\mu\text{m}$ and $1100 \text{ }\mu\text{m}$, the side faces 32c and 32d enclosing an average slope angle in the range between 0.5° and 1.5° .

CLAIMS:

1. An auditive prosthesis comprising an elongated carrier which can be implanted in the scala tympani of a cochlea, which carrier is provided, over at least a part of its length, with electrode elements at a first side face and, at a second side face facing away from the first side face, with an electric conductor, which side faces are interconnected by a third side face and a fourth side face, the first side face extending, in a state in which the carrier is implanted in the scala tympani, opposite the basilar membrane of the cochlea, characterized in that, over at least a part of the length of the carrier where electrode elements are present, the third side face and the fourth side face of the carrier are situated at distances from each other which are at least substantially equal to corresponding dimensions of the scala tympani which extend parallel to the basilar membrane, in order to at least substantially completely fill the scala tympani, after implantation, over at least a part of the area extending between the fenestra cochlea and the helicotrema in a zone extending parallel to the basilar membrane.
2. An auditive prosthesis as claimed in claim 1, characterized in that, over at least the part of the carrier where electrode elements are present, the first side face and the second side face of the carrier are at distances from each other which are at least substantially equal to corresponding dimensions of the scala tympani which extend transversely to the basilar membrane, in order to at least substantially completely fill the scala tympani, after implantation, over at least a part of the area extending between the fenestra cochlea and the helicotrema in a zone extending transversely to the basilar membrane.
3. An auditive prosthesis as claimed in claim 1, characterized in that the carrier has a base and a top, the distances between the third side face and the fourth side face decreasing in the direction of said top, the third side face and the fourth side face extending at a mutual distance between 900 μm and 1100 μm in a central area of the part where electrode elements are present, and the third side face and the fourth side face enclosing an average slope angle ranging between 0.5° and 1.5°.

4. An auditive prosthesis as claimed in claim 2, characterized in that the carrier has a base and a top, the distances between the first side face and the second side face decreasing in the direction of said top, the first side face and the second side face extending at a mutual distance ranging between 700 μm and 900 μm in a central area of the part where
5 electrode elements are present, and the first side face and the second side face enclosing an average slope angle ranging between 0.5° and 1.5°.
5. An auditive prosthesis as claimed in claim 1, characterized in that the first side face of the carrier forms a surface, the electrode elements being provided with flat contact
10 faces which are situated in or below the above-mentioned surface.
6. An auditive prosthesis as claimed in claim 5, characterized in that the contact faces of the electrode elements are arranged according to a series extending in the longitudinal direction of the carrier, at least a number of the contact faces present being oval faces, whose
15 longitudinal axes are oriented transversely to the longitudinal direction of the carrier.
7. An auditive prosthesis as claimed in claim 5, characterized in that the contact faces of the electrode elements have a rough surface.
- 20 8. An auditive prosthesis as claimed in claim 1, characterized by the presence of a microphone and a speech processor.
9. A carrier which can suitably be used in the auditive prosthesis as claimed in any one of the preceding claims, which carrier is characterized as described in any one of the
25 claims 1 through 7.
10. A carrier which can suitably be implanted in a cochlea, which carrier is embodied so as to be elongated and is provided, over at least a part of its length, at a first side face, with electrode elements, characterized in that the first side face forms a surface, the
30 electrode elements being provided with flat contact faces which are situated in or below said surface.
11. A carrier as claimed in claim 10, characterized in that the contact faces of the electrode elements are arranged in accordance with a series extending in the longitudinal

direction of the carrier, at least a number of the contact faces present being oval faces whose longitudinal axes are oriented transversely to the longitudinal direction of the carrier.

12. A carrier as claimed in claim 11, characterized in that the contact faces of the
5 electrode elements have a rough surface.

13. A carrier as claimed in claim 10, characterized in that the carrier is provided, at
a second side face facing away from the first side face, with an electric conductor which
comprises electrode faces, which are situated in or below a surface formed by the second side
10 face.

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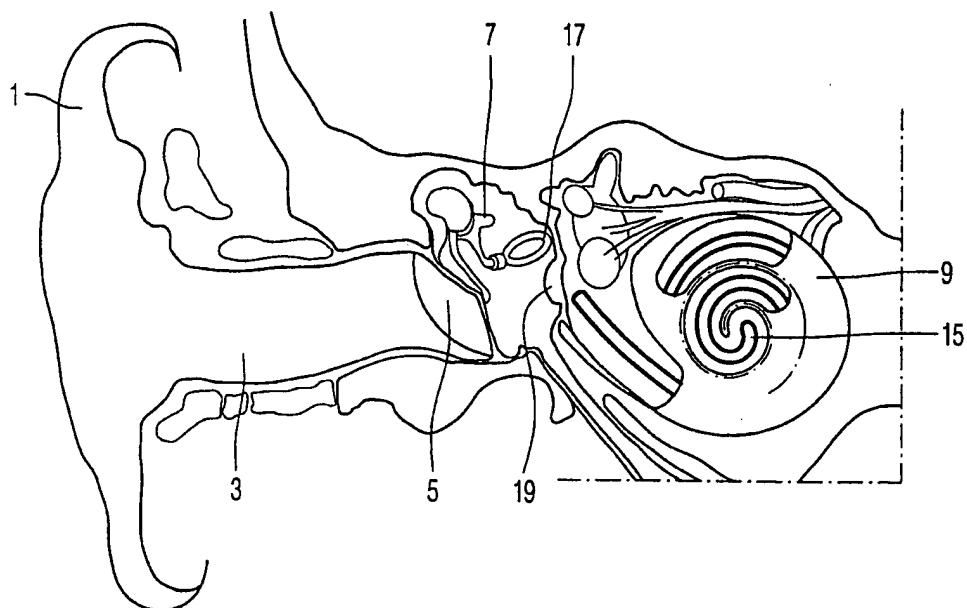


FIG. 1

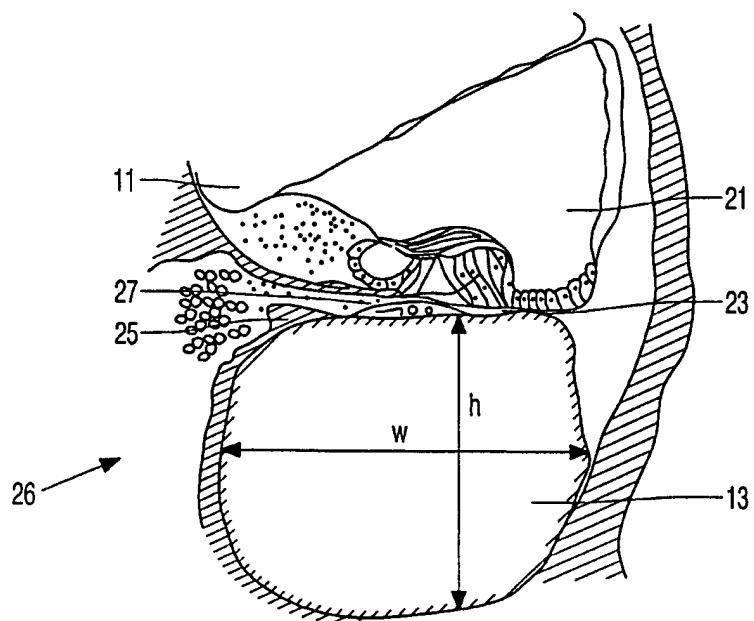


FIG. 2

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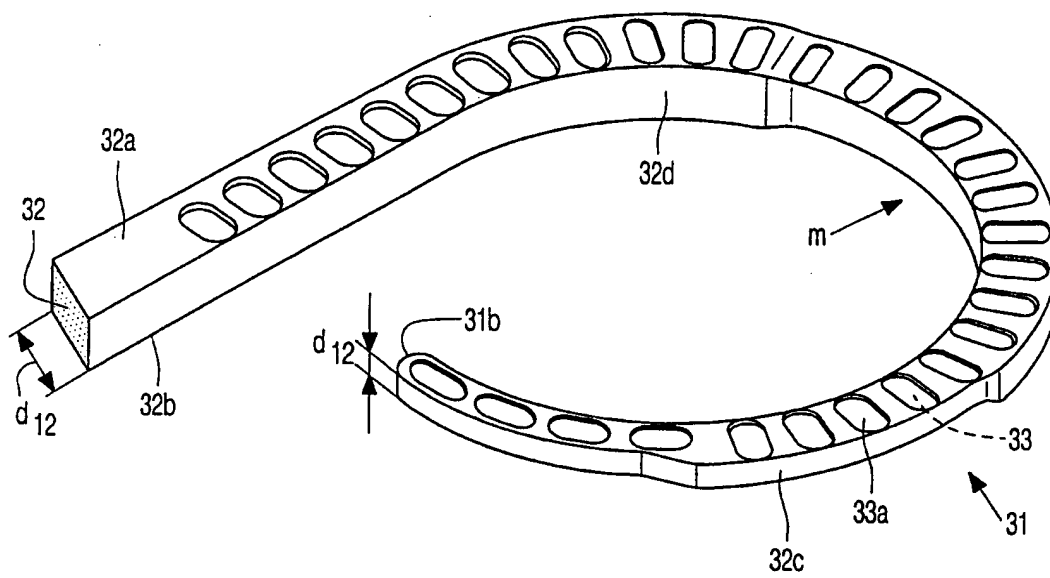


FIG. 3

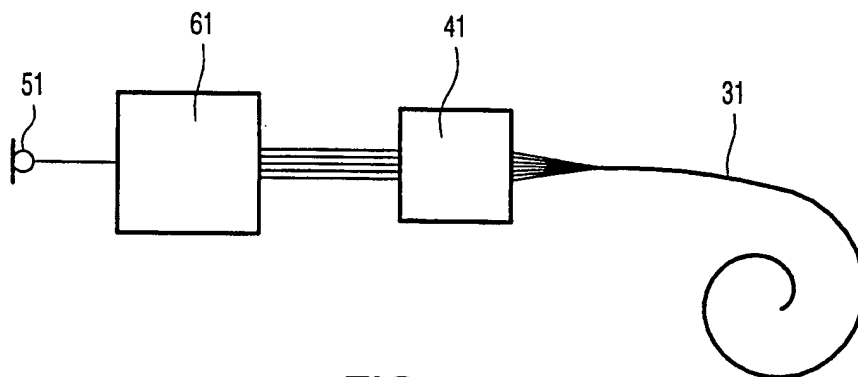


FIG. 6

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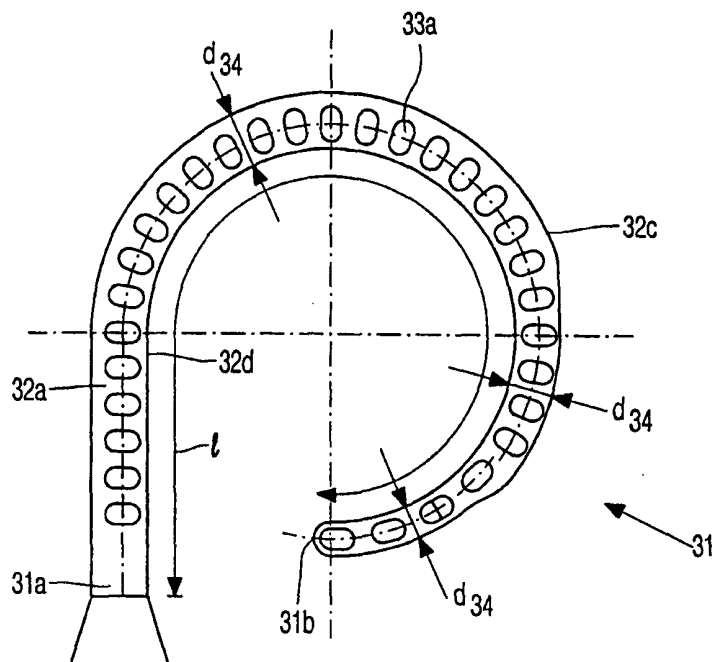


FIG. 4

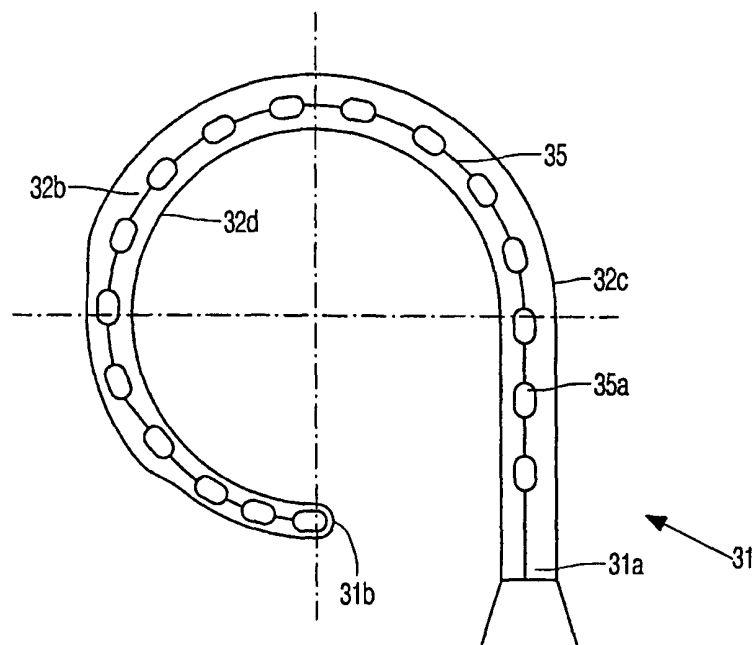


FIG. 5